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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,815	12/07/2000	Akira Aomatsu	5836-01-MJA	5030

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Charles W Ashbrook  
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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

22

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/674,815

Applicant(s)

AOMATSU, AKIRA

Examiner

Brian S Kwon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application***

By amendment filed September 10, 2003, Claims 10-17 have been cancelled and Claims 1, 9, 18, 20 and 24 have been amended. Claims 1-9 and 18-24 are currently pending for prosecution on the merits.

### ***Summary of Action***

- I. The rejection of claims 1-9 and 23-24 under 35 USC 112, first paragraph, will not be maintained in light of the amendment.
- II. The rejection of claims 18 and 20 under 35 USC 102(b) as being anticipated by Woodruff will be maintained for the reason of the record.
- II. The rejection of claims 1-9, 19, 21-22 and 24 under 35 USC 103(a) will be maintained for the reason of the record.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodruff (US 5084479).

This rejection is analogous to the original rejection.

### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 19, 21-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seiler et al. (Gen. Pharmac. Vol. 15, No. 4, pp. 367-369, 1984) in view of Costa et al. (US 5248678).

This rejection is analogous to the original rejection.

### ***Response to Arguments***

Applicant's arguments filed September 10, 2003 have been fully considered but they are not persuasive.

Applicant's argument takes position that Woodruff does not anticipate the claimed invention since the reference does not teach the inclusion of "an auxiliary agent for manufacturing a pharmaceutical preparation". This argument is not persuasive since the referenced solution comprising N-methyl-D-aspartic acid and gabapentin in water still reads on

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the claimed invention. Water is a well-known auxiliary agent that is routinely used in a pharmaceutical preparation (US 3692902, US 5075301 and US 3935326).

Applicant's argument takes position that Seiler fails to teach or suggest the claimed pharmaceutical preparation comprised of gabapentin and an alpha amino acid since Seiler warns against administering muscimol and glycine together so as "to avoid the potential inhibition of muscimol absorption by glycine". The examiner disagrees. Although the Seiler concerns about the potential inhibition of muscimol absorption by glycine, the Seiler only refer to the potential decrease in absorption of muscimol by glycine in subcutaneous administration. In examiner's opinion, the Seiler does not refer to the unsuitability of GABA agonist and alpha amino acid in a composition as applicant alleged. In fact, the numerous prior art references (US 4540582; 4595697; Liu et al., "Potentiation of  $\gamma$ -vinyl GABA (vigabatrin) effects by glycine", European Journal of Pharmacology, 182 (1990), 109-115; Peterson et al., "Potentiation by Glycine of Anticonvulsant Drugs in Maximal Electroshock Seizures in Rats", Neuropharmacology, Vol. 29, No. 4, pp. 399-409) teaches or suggests the pharmaceutical preparation comprising GABA agonist and glycine. Unlike applicants' argument, the prior art references clearly teach the synergistic anticonvulsant effect of GABA agonist and glycine. Furthermore, the prior art references make clear that gabapentin and glycine have been individually used for the treatment of seizure disorders. Therefore, it would have been obvious to one having ordinary skill in the art to arrive at the claimed invention, with reasonable expectation of success, since the combination of gabapentin and glycine in a composition would provide synergistic anticonvulsant effect.

***-Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

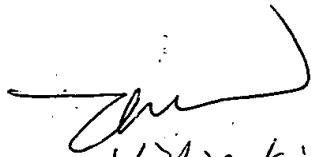
Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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Brian Kwon

  
Vidhe Kim  
~~ZOHREH FAY~~  
**PRIMARY EXAMINER**  
**GROUP 1600**